

24. QUESTION 24

The epidemiological study utilising the UK General Practice Research database (GPRD) seems like a potentially informative study. More information is required, however, about the study (i.e. study protocol) and a timetable indicating when the first sets of results will be analysed and when a report of results can be expected.

Response

24.1. Study Protocol

The full protocol for our study, "Paroxetine, SSRI Use and the Risk of Suicidal Behaviour", is contained as [Appendix 24](#) of this response. This document updates a previous version of the study protocol.

24.2. Study Timetable

Analyses are currently ongoing, with preliminary results expected during March 2004, and a final report expected to be completed in April, 2004. A sample of suicidal events are being validated by the GPRD division of the MHRA. This validation study was started on December 13th, 2003 and the final results are not expected from the MHRA before April. All analyses will be finalised following receipt of these data. It should be noted that these timelines differ from those given in a previous version of the study protocol.